

endoret[®] (proF[®])

Endogenous Regenerative Technology

ORAL SURGERY



www.bti-biotechnologyinstitute.com



bti[®]
Human
Technology



LEADER IN REGENERATIVE MEDICINE

BTI Biotechnology Institute is a Spanish biomedicine company focused on the development of translational research projects (R&D+i).

BTI is a world-level scientific leader in regenerative medicine using Endoret in different fields of medicine.

**MORE THAN 5000 M² DEVOTED TO TRAINING, CLINICAL PRACTICE
AND RESEARCH**

.....



WE TRAIN IN ORDER TO OPTIMISE THE CLINICAL RESULTS

- **Specific training** aimed at different medical specialities.
- **More than 40 scientific collaboration agreements** with universities and research institutes all over the world.
- **More than 1200 students** per year of all nationalities.

TRANSLATIONAL RESEARCH: KNOWLEDGE ACQUIRED IN THE LABORATORY APPLIED TO CLINICAL PRACTICE

- **Collaboration with experts from different countries** in different fields of medicine for the development of clinically effective protocols.

MORE THAN 150 INDEXED SCIENTIFIC PUBLICATIONS BACK THE EFFECTIVENESS AND BIOSAFETY OF ENDORET®

- **20% of the workforce** dedicated to research.
- **More than 15 years of research** in tissue regeneration.

ENDORET® TECHNOLOGY

1. WHAT IS IT?

ENDORET® IS A BIOMEDICAL TECHNOLOGY AIMED AT STIMULATING TISSUE REGENERATION BY APPLYING AUTOLOGOUS PROTEINS.

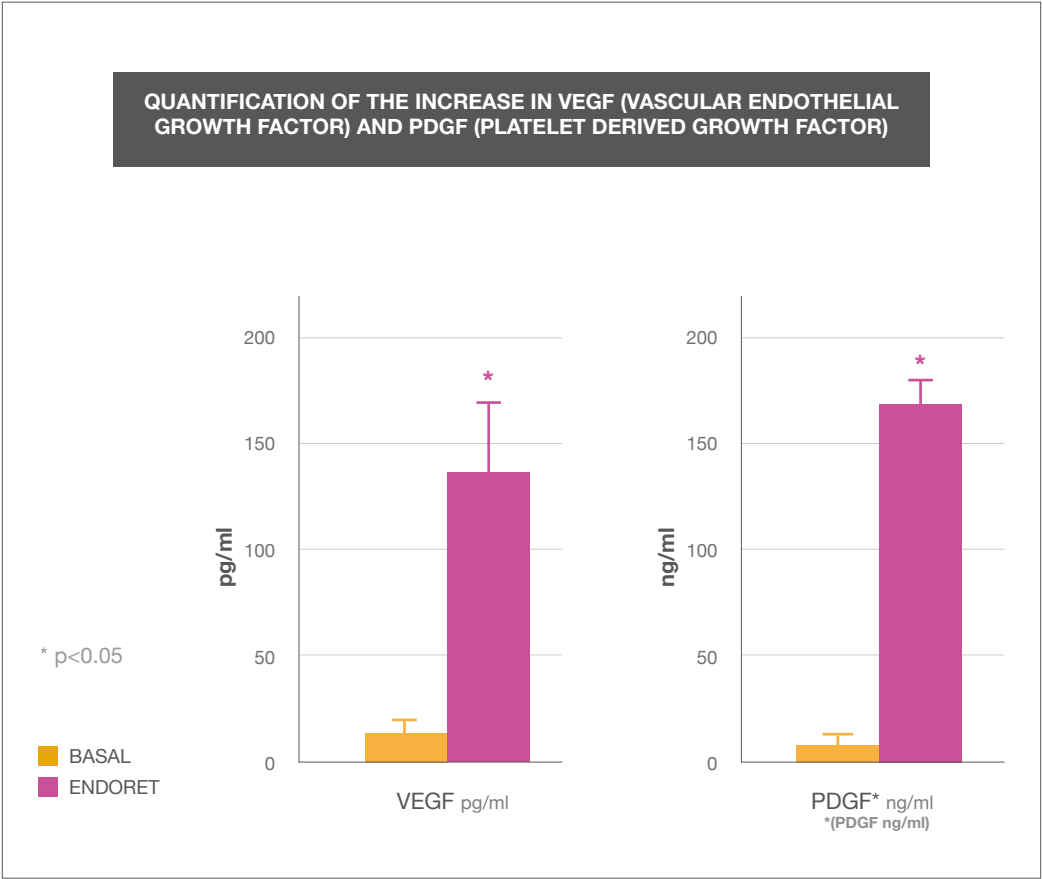
Hundreds of endogenous proteins affect the tissue repair processes, including angiogenesis, chemotaxis and cell proliferation. No exogenic agent can effectively govern all these processes.⁽¹⁾

Endoret technology provides the necessary means for obtaining plasma rich in growth factors from whole blood.

2. PROTEINS AND AUTOLOGOUS MATRIX

A. GROWTH FACTORS

ENDORET stimulates tissue regeneration due to enrichment with growth factors, acting as a biological system. ⁽²⁾



B. FIBRIN MEMBRANE

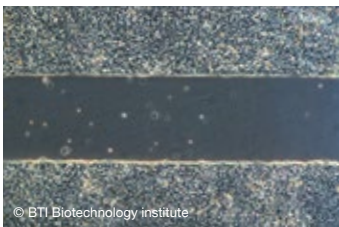
Enables the balanced and gradual release of a large number of molecules, including growth factors and other proteins. ^{(3) (4) (5)}

3. REGENERATIVE POTENTIAL

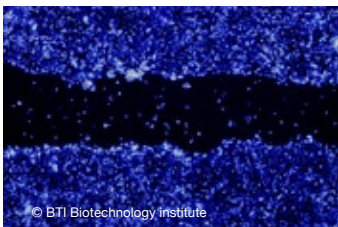
- Promoting **angiogenesis (A)**.⁽⁶⁾
- Stimulating **cell migration (B)**.⁽⁷⁾
- Increasing the **proliferation (B)**.⁽⁷⁾⁽⁸⁾⁽⁹⁾
- Decreasing **inflammation and pain(C)**.⁽¹⁰⁾⁽¹¹⁾⁽¹²⁾
- Stimulating **autocrine and paracrine secretion of growth factors (B)**.⁽⁷⁾⁽⁸⁾⁽⁹⁾

(A) Pre-clinical study (B) In vitro study (C) Clinical study

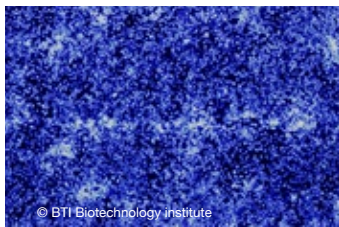
ENDORET ACCELERATES CELL MIGRATION FOR REGENERATIVE PURPOSES ⁽⁷⁾⁽⁸⁾



INITIAL STATUS (0H.)



CONTROL (24H.)

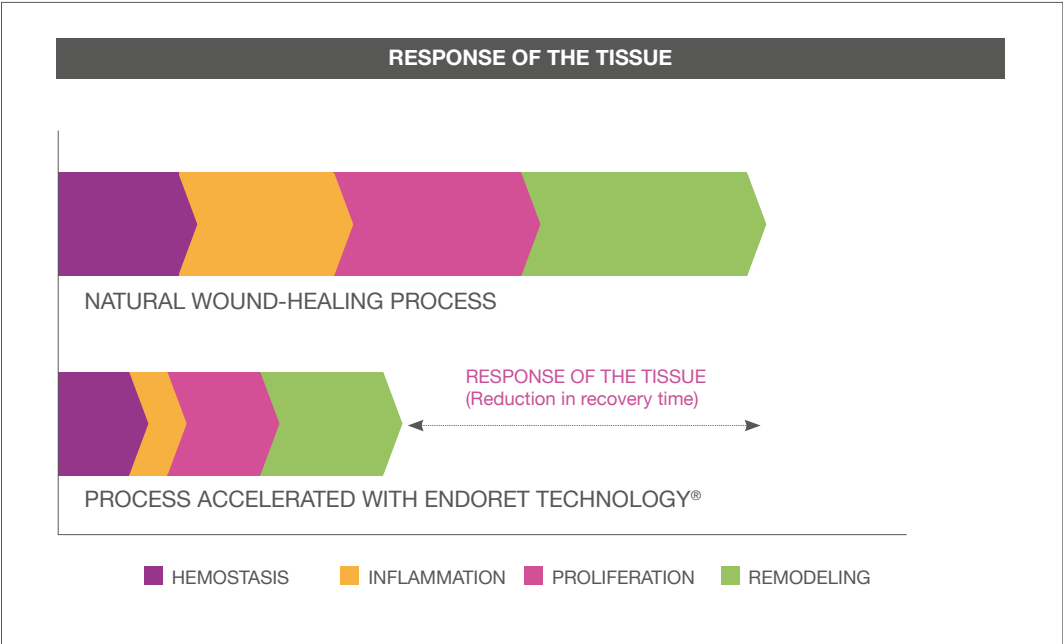


ENDORET® (24H.)

ENDORET® TECHNOLOGY REDUCES THE TISSUE REPAIR TIME IN CLINICAL TRIALS. ^{(13) (14)}



SCAN THE CODE WITH YOUR SMARTPHONE TO WATCH THIS VIDEO

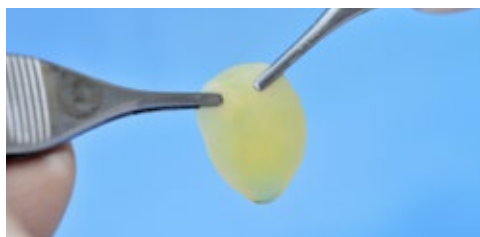


4. VERSATILITY

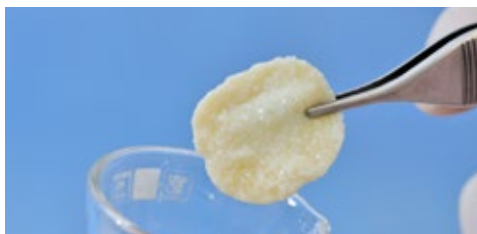
The versatility of the Endoret technology allows for its use in different clinical applications.⁽¹⁵⁾



Liquid



Clot



Agglutinating a biomaterial/ graft



Fibrin membrane

5. SAFETY

Autologous product, there are no incompatibilities **nor risk of rejection**.

All the formulations of ENDORET have a **bacteriostatic effect**, especially during the 4 hours after application (in vitro studies). ^{(16) (17)(18)}

More than 700,000 patients have been treated in more than 20 countries, **without any adverse effects being reported**.

BENEFITS AND APPLICATIONS OF ENDORET TECHNOLOGY® IN IMPLANTOLOGY

1. INCREASED PREDICTABILITY

BTI IMPLANTS WETTED WITH ENDORET HAVE A HIGH SURVIVAL RATE.⁽¹⁹⁾⁽²⁰⁾⁽²¹⁾⁽²²⁾

When the surface of the implants is wetted with ENDORET liquid, a fibrin membrane is formed and adheres to the surface of the implant, releasing growth factors and improving the osseointegration.

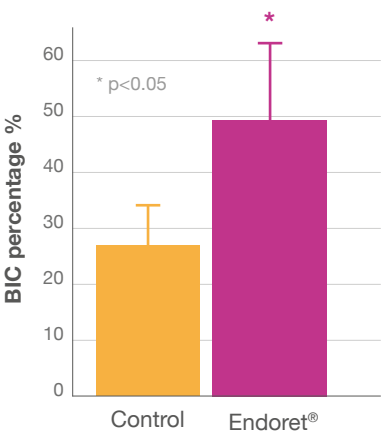
The nano-rough surface of BTI implants is specially designed to boost the biological effects of ENDORET.

WETTING WITH ENDORET INCREASED THE TRABECULAR THICKNESS AND MATURITY OF THE BONE

SURVIVAL RATES REPORTED IN CLINICAL STUDIES:

- Up to 5 years follow-up study
5787 implants. **99.2%** ⁽¹⁹⁾
- Up to 5 years follow-up study
1139 immediate load implants. **99.3%** ⁽¹⁷⁾
- Up to 8 years follow-up study
1287 short implants. **99.3%** ⁽¹⁸⁾
- 10-12 years follow-up study
111 short implants. **98.9%** ⁽²²⁾

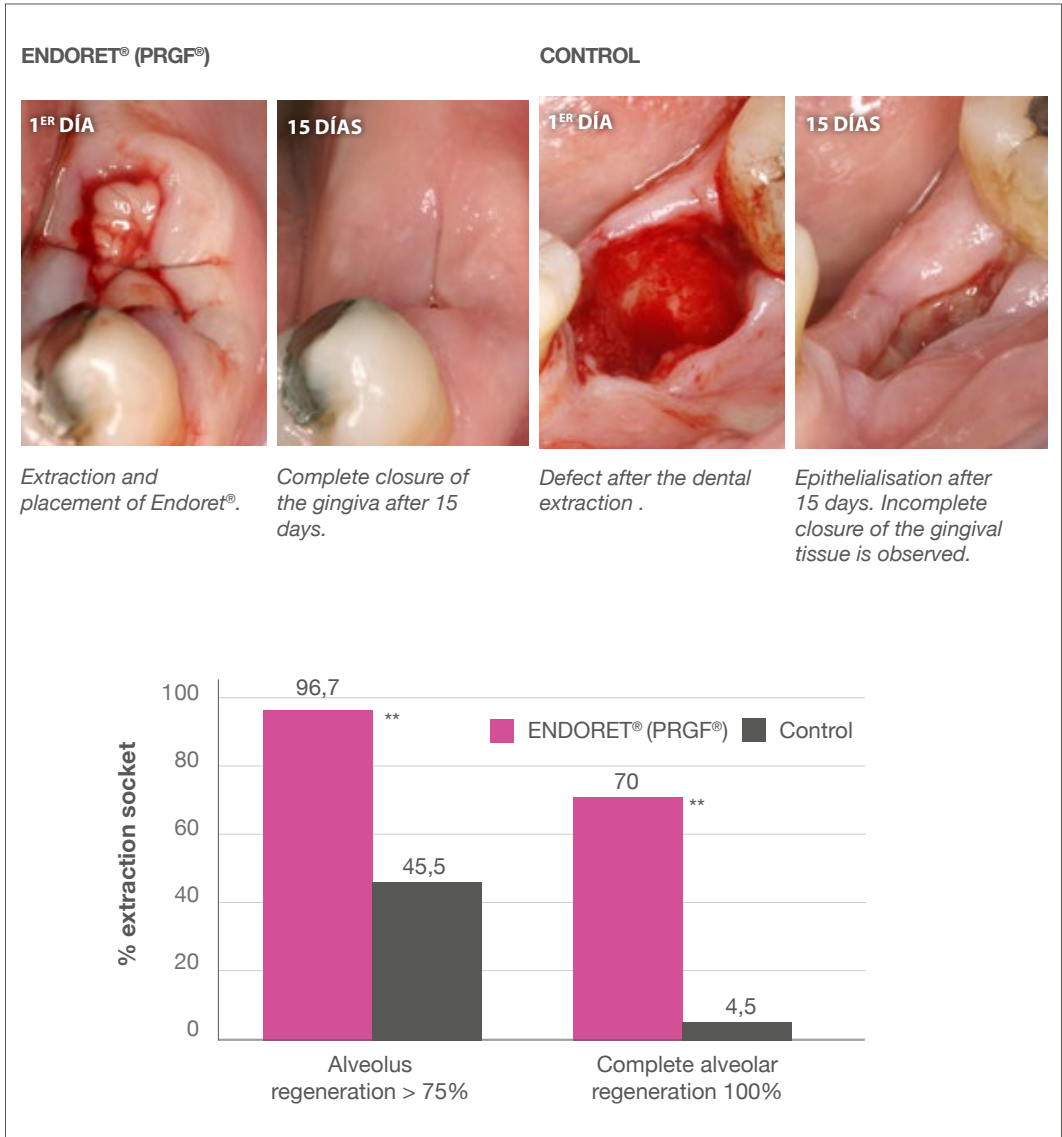
HISTOMORPHOMETRIC EVALUATION OF THE BONE-IMPLANT CONTACT SURFACE (BIC) AFTER TWO MONTHS IN GOATS ⁽²³⁾



2.TREATMENT OF POST-EXTRACTION SOCKET

The application of Endoret® in the treatment of post-extraction socket reduces inflammation and pain, **accelerates** soft tissues healing and **promotes bone regeneration** as it has been demonstrated in several clinical trials. ^{(11) (14) (24)}

The survival rate of immediately placed dental implant, after tooth extraction, has been 98% in a clinical study. It is a safe, effective and predictable treatment. ⁽²⁵⁾



3. REDUCED RISK OF OSTEONECROSIS


The results of various clinical studies suggest that treatment with ENDORET can reduce the risk of BRONJ after a dental extraction in high-risk patients under treatment with bisphosphonates. ⁽²⁷⁾⁽²⁸⁾

TREATMENT	NUMBER OF EXTRACTIONS	OSTEONECROSIS OF THE MAXILLA
Control	267	5
Endoret® (PRGF®)	542	0

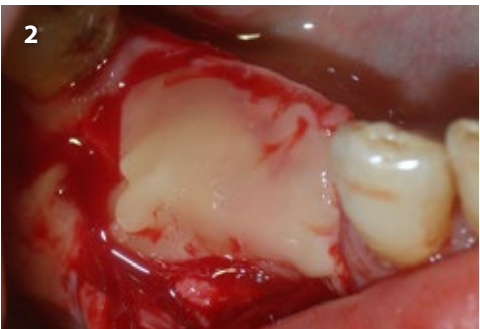
CLINICAL TRIAL OF THE PREVENTION OF BISPHOSPHONATE-ASSOCIATED OSTEONECROSIS OF THE JAW (BRONJ) ⁽²⁷⁾

ENDORET® (PRGF®)

1




2

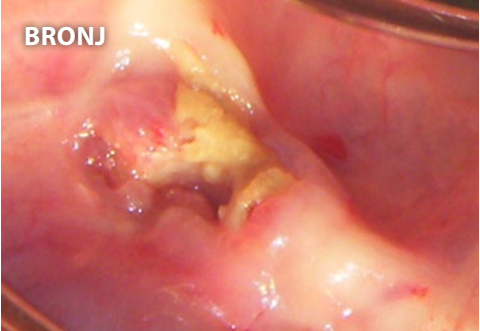


CONTROL

3



BRONJ



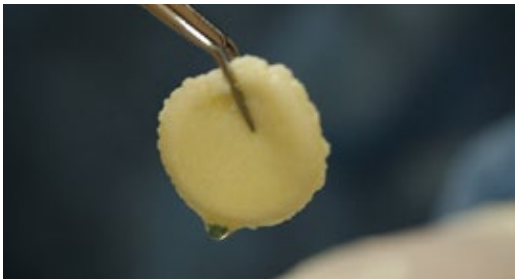
4. ENDORET® IN THE TREATMENT OF BRONJ

Treatment with ENDORET, after resecting the necrotic bone of BRONJ, may enhance vascularization and regeneration of bone and epithelial tissue as shown in a clinical trial. ⁽²⁶⁾

Endoret was effective in the surgical treatment of bisphosphonate-associated osteonecrosis of the jaw, achieving closure of the defect in 32 patients in a clinical prospective study. ⁽²⁶⁾

5. PREPARATION OF GRAFTS

ENDORET can be used to **agglutinate a biomaterial, making it easier to handle** and improving its osteoconductive and biological properties. ⁽¹⁰⁾⁽²⁹⁾⁽³⁰⁾⁽³¹⁾⁽³²⁾

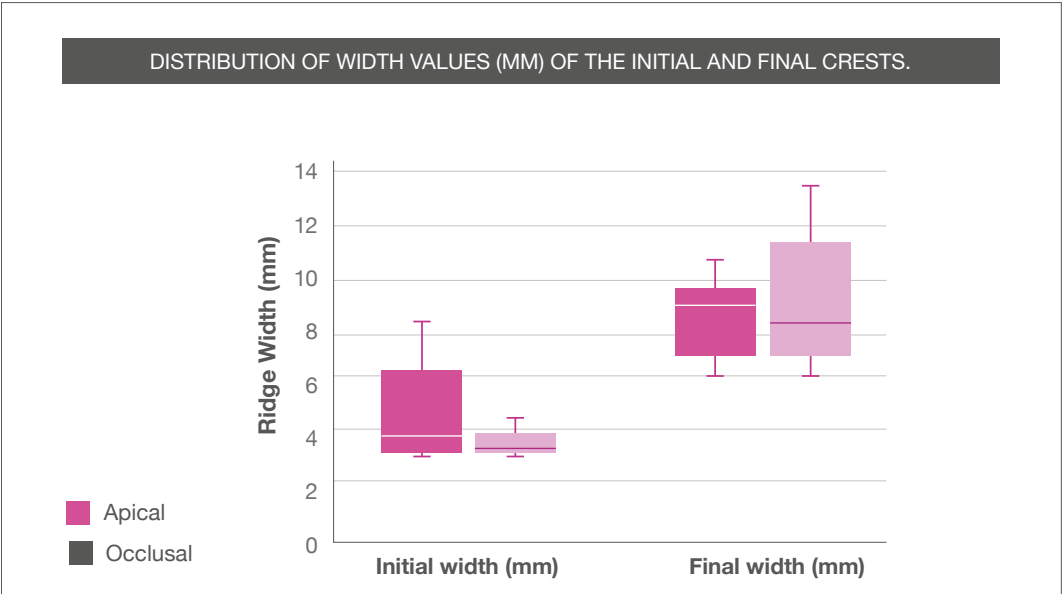


6. TREATMENT OF ATROPHIC MAXILLAE

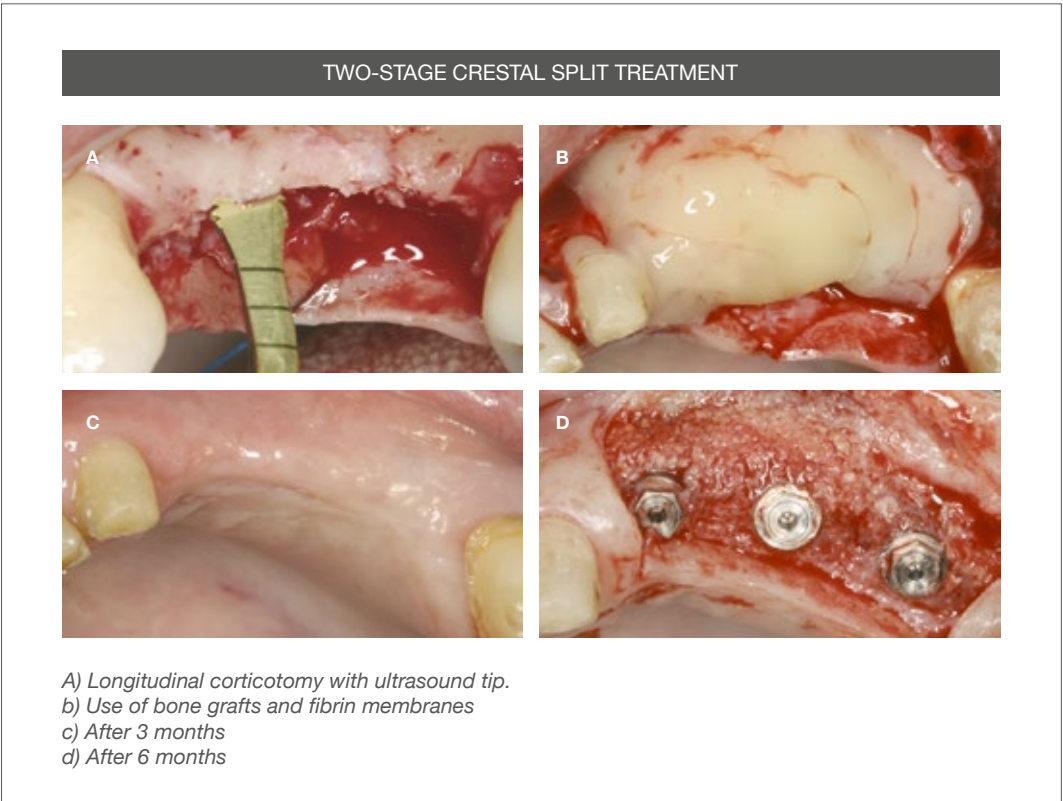
ENDORET improves the tissue regeneration and due to its versatility can be used in various surgical techniques.

A. LATERAL BONE AUGMENTATION

The alveolar ridge expansion and the alveolar ridge split techniques in combination with ENDORET® can achieve an average bone expansion of 3.35 mm.⁽³³⁾⁽³⁴⁾



The use of ENDORET® in combination with the block graft improves the tissue healing, avoiding the exposure of the graft and improves the post-operative recovery of the patient.⁽³⁵⁾



B. SINUS ELEVATION


ENDORET reduces inflammation and pain. It increases the new bone formation.⁽¹⁰⁾⁽³¹⁾⁽³⁶⁾

ENDORET is effective in the treatment of perforations in the Schneider membrane.⁽³⁰⁾


SPLIT-MOUTH STUDY OF ENDORET VS. CONTROL IN A SINUS ELEVATION
PROCEDURE WITH A LATERAL APPROACH. ⁽³²⁾

CONTROL


ENDORET® (PRGF®)



ENDORET® INCREASES
THE FORMATION OF MATURE BONE



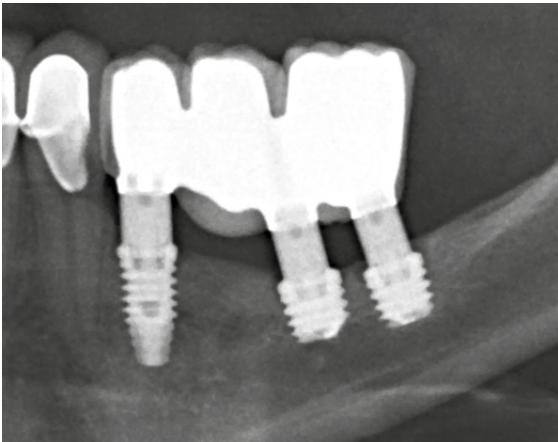
Control treatment



treatment with ENDORET®

C. VERTICAL BONE REGENERATION

The combination of Endoret graft with short and extra-short implants makes possible the rehabilitation of atrophic mandible without the need of more aggressive techniques. ⁽³⁷⁾⁽³⁸⁾



7. PERIODONTAL REGENERATION

ENDORET may be beneficial in the field of the mucogingival surgery.⁽³⁹⁾



Treatment of gingival defects

COMPONENTS OF ENDORET TECHNOLOGY®

1. ENDORET® DISPOSABLE KIT SINGLE-USE KIT*

* MEDICAL DEVICES CERTIFIED FOR APPLICATION IN THE REGENERATION OF
SOFT AND HARD TISSUES FOR ORAL SURGERY.

KIT KMU15

- 4 extraction tubes
- 2 fractioning tubes
- 1 ampoule of activator
- 1 activation syringe
- 1 PTD 2
- 1 winged blood collection set
- 5 identification labels

10 BLISTER PACKS FOR INDIVIDUAL
TREATMENTS

PLUS ONE BLISTER PACK WITH
ADDITIONAL MATERIAL:

- 8 extraction tubes
- 4 fractioning tubes
- 2 ampoules of activator



KIT KMU15 PLUS

- 8 extraction tubes
- 4 fractioning tubes
- 2 ampoules of activator
- 1 activation syringe
- 1 PTD 2
- 1 winged blood collection set
- 5 identification labels

10 BLISTER PACKS FOR INDIVIDUAL
TREATMENTS

KIT KMU16

- 1 winged extraction set
- 4 BTI tubes - no additives.
- 2 fractioning tubes
- 1 PTD
- 5 identification labels

New kit designed to carry out
the treatments of the socket
post-extraction in fewer steps.

15 BLISTER PACKS FOR
INDIVIDUAL TREATMENTS

2. EQUIPMENT

- Centrifuge System V
- Plasmaterm H

START PTD0 KIT

- Work rack
- Activation containers (ø50 mm).
- Digital timer unit.
- KMU15 Kit



FIBRINE MEMBRANE SHAPER

Composed of 2 pieces: basis, to be placed on the activation container* and lid, used for compressing the plasma clot once deposited on the basis. Made of stainless steel.

A weight* is placed on the lid to obtain a more homogenous membrane.

** The activation container and the weight are sold separately.*



3. TRAINING

Exclusive training adapted to medical needs. We share our new clinical research and provide training for innovative, top-quality healthcare.

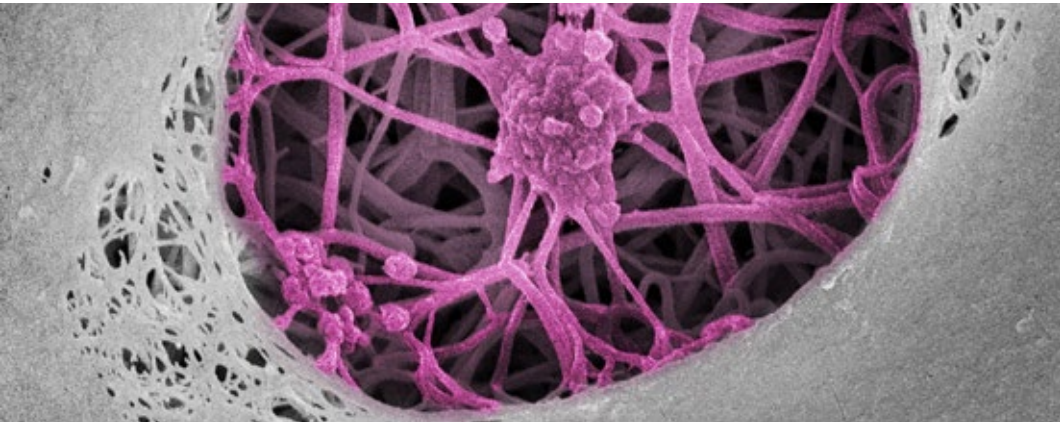
4. CERTIFICATION

We certify the clinical qualification and experience of our customers with our training certificates.



ADVANTAGES OF ENDORET TECHNOLOGY®

ENDORET is the technology with the most experience on the market in the development of specific protocols for tissue regeneration, a pioneering technology manufactured exclusively by BTI Biotechnology Institute.



OPTIMUM CONCENTRATION OF PLATELETS

The right concentration of platelets affects the final efficacy. ^{(2) (40)}

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FORMULATION FREE OF LEUKOCYTES

The inclusion of leukocytes increases the pain and inflammation ⁽⁴¹⁾ and accelerates the deterioration of the fibrin. ⁽⁴²⁾

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CONTROLLED ACTIVATION

Enables the formation of the fibrin matrix in situ and the gradual release of growth factors, maintaining its efficacy over time. ^{(4) (43)}

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AUTOLOGOUS

It is made from the patient's own blood, so there are no known adverse effects. ⁽⁴⁴⁾

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REPRODUCIBLE

The protocol for the preparation process and its clinical application is strictly defined and tested.

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VERSATILE

4 preparations that can adapt the product to the clinical needs. ⁽¹⁵⁾⁽⁴⁵⁾

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SAFETY AND REGULATORY ASSURANCE

QUALITY ASSURANCE

- The ENDORET system complies with the highest standards of quality. The protocol for the preparation of ENDORET is described in detail in the Manual for Use contained in each ENDORET PRGF Kit.
 - Both the system and the materials have the CE health certificate for specific application to oral surgery.
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GUARANTEES OF EFFICACY

- BTI has the greatest clinical support in the world published in this field; its effectiveness is proven in more than 150 international scientific publications.
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ADDITIONAL GUARANTEES

- BTI certifies its customers' specific training in the use of this technology.
- In addition, BTI guarantees the traceability of its materials, and helps transfer all necessary information to its patients.



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